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	Application No.	Applicant(s)	
	09/308,407	KOCH ET AL.	
Notice of Allowability	Examiner	Art Unit	
	Michael C. Miggins	1772	
The MAILING DATE of this communication app All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85 NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R of the Office or upon petition by the applicant. See 37 CFR 1.31	S (OR REMAINS) CLOSED i i) or other appropriate comm RIGHTS. This application is	n this application. If not included unication will be mailed in due cour	se. THIS
1. X This communication is responsive to 4/22/05.			
2. The allowed claim(s) is/are 18,19,22,23 and 25-32.			
3. $igotimes$ The drawings filed on $\underline{ extit{19 May 1999}}$ are accepted by the E	xaminer.		
4. Acknowledgment is made of a claim for foreign priority uses) All b) Some* c) None of the:  1. Certified copies of the priority documents have 2. Certified copies of the priority documents have 3. Copies of the certified copies of the priority documents have International Bureau (PCT Rule 17.2(a)).  * Certified copies not received:  Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONITHIS THREE-MONTH PERIOD IS NOT EXTENDABLE.  5. A SUBSTITUTE OATH OR DECLARATION must be submin INFORMAL PATENT APPLICATION (PTO-152) which give 6. CORRECTED DRAWINGS (as "replacement sheets") must be comply including changes required by the Notice of Draftsper 1) hereto or 2) to Paper No./Mail Date  (b) including changes required by the attached Examiner Paper No./Mail Date  Identifying indicia such as the application number (see 37 CFR each sheet. Replacement sheet(s) should be labeled as such in 7. DEPOSIT OF and/or INFORMATION about the deposition of the control of the deposition o	re been received. re been received in Application received in Application received in Application received in Application received received in Application received received in Application received received in Application r	on No  d in this national stage application to a reply complying with the require  AMINER'S AMENDMENT or NOTIC or declaration is deficient.  w ( PTO-948) attached  r in the Office action of the drawings in the front (not the back FR 1.121(d).  ERIAL must be submitted. Note	ments CE OF
attached Examiner's comment regarding REQUIREMENT	FOR THE DEPOSIT OF BI	OLOGICAL MATERIAL.	
Attachment(s)	5   Nation of t	nformal Patent Application (PTO-15	2)
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Dotice of Draftperson's Patent Drawing Review (PTO-948)</li> </ol>		Summary (PTO-413),	<i>-</i> j
Information Disclosure Statements (PTO-1449 or PTO/SB/	Paper No.	/Mail Date <u>05122005</u> . : Amendment/Comment	
Paper No./Mail Date	, –		
<ol> <li>Examiner's Comment Regarding Requirement for Deposit of Biological Material</li> </ol>	8. ⊠ Examiners	Statement of Reasons for Allowan  -  Auchael ( Auchael )	ce
		MICHAEL C. MIGGINS PRIMARY EXAMINER	



#### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Peter Hochberg on 5/12/2005.

The application has been amended as follows:

## In the specification:

On page 1, after the title "DESCRIPTION" and before line 1 of the text the subtitle - - FIELD OF INVENTION - - has been inserted.

On page 1, in between lines 4 and 5 of the text the sub-title - - BACKGROUND OF INVENTION - - has been inserted.

On page 2, before line 1 of the text the sub-title - - SUMMARY OF INVENTION - - has been inserted.

On page 4, in between lines 11 and 12 of the text the sub-title - - BRIEF DESCRIPTION OF DRAWINGS - - has been inserted.

On page 4, in between lines 14 and 15 of the text the sub-title - - DETAILED

DESCRIPTION OF THE INVENTION - - has been inserted.

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# In the claims:

Claims 20-21 and 24 are canceled.

In claim 18, line 1, after "A" and before "packaging system" the term - - sealed - - has been inserted.

In claim 18, lines 1-2, after "packaging material" and before "a product" the phrase "for the sealed enclosure of" has been deleted and the phrase - - which contains - has been inserted in place thereof.

In claim 18, line 2, after product having and before active ingredients the term - - volatile - - has been inserted.

In claim 18, lines 2-3, after "active ingredients" and before ", said composite material" the phrase "possibly being volatile and/or ancillary substances" has been deleted.

In claim 18, line 3, after "material having" and before "uptake of active" the phrase "a strength, no significant" has been deleted and the phrase - - a strength and no significant - - has been inserted in place thereof.

In claim 18, lines 4-5, after "of the product" and before ", said packaging system" the phrase "and having no or reduced interactivity with the active ingredients and the ancillary substances of the product" has been deleted.

In claim 18, line 7, the term "including" has been deleted and the term - - comprising - - has been inserted in place thereof.

In claim 18, lines 13-14, after "applicable with" and before "printing machines," the phrase "conventional simple" has been deleted.

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In claim 18, line 15, before "uptake of the active ingredient;" the phrase "enabling an insignificant" has been deleted and the phrase - - having no significant - - has been inserted in place thereof.

In claim 18, line 19, after "strength in" and before "strength" the phrase "the region of the" has been deleted and the phrase "a region of" has been inserted in place thereof.

In claim 18, line 21, after "wherein" and before "layers" the term "the" has been deleted.

In claim 19, the entire text has been deleted and the following text has been inserted in place thereof:

- - A packaging system according to claim 18 wherein the heat sealing lacquer layers cover only the sealing area. - -

In claim 23, lines 3-6, after "active ingredient" the phrase ", for forming an adhesive melt phase with comparatively small exposure to heat for a short period of time when applied in an extremely thin sealing layer, when compared with a heat-sealing medium applied in a relatively thicker sealing layer" has been deleted.

In claim 26, line 1, after "claim 18" the phrase "wherein said layers comprise" has been deleted and the term - - comprising - - has been inserted in place thereof.

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In claim 28, after "claim 18" the phrase "wherein said layers comprise" has been deleted and the term - - comprising - - has been inserted in place thereof.

### Reasons for Allowance

2. The following is an examiner's statement of reasons for allowance:

With regard to instant claim 18, the prior art fails to teach or suggest a sealed packaging system composed of composite packaging material which contains a product having volatile active ingredients, said packaging system comprising layers defining a space for holding the product between said layers, said layers comprising barrier layers on opposite sides of the space holding the product forming a barrier against volatile active ingredients and heat-sealing lacquer layers between said respective opposite barrier layers, said heat-sealing lacquer layers having a weight per unit area in the range of between 1 and 15 grams per meter squared.

The closest prior art is Wardell (US 3938659) and Hunt et al. (US 5077104).

Wardell discloses a sealed packaging system composed of composite packaging material which contains a product (sterilized pharmaceutical products), said packaging system comprising layers defining a space for holding the product between said layers and heat-sealing lacquer layers between said respective opposite barrier layers.

Wardell does not disclose that the product has volatile active ingredients, said layers comprising barrier layers on opposite sides of the space holding the product forming a barrier against volatile active ingredients, said heat-sealing lacquer layers having a weight per unit area in the range of between 1 and 15 grams per meter squared.

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Wardell teaches away from a package containing a product which has volatile active ingredients since the packaged products are sterilized. Moreover, Wardell specifically teaches away from said heat-sealing lacquer layers having a weight per unit area in the range of between 1 and 15 grams per meter squared. Applicant specifically states that the thickness of the lacquer is critical and it is to be very thin (instant spec, page 2<sup>nd</sup> and third full paragraphs, page 2, 3<sup>rd</sup> full paragraph, page 3, 3<sup>rd</sup> full paragraph) to prevent uptake of active ingredients and to lower production costs as opposed to Wardell who discloses a very thick lacquer layer (column 6, lines 33-45).

Hunt et al. disclose a sealed packaging system composed of composite packaging material which contains a product having volatile active ingredients (nicotine pouch), said layers comprising barrier layers on opposite sides of the space holding the product forming a barrier against volatile active ingredients and a space for holding the product. However, Hunt et al. fail to disclose heat-sealing lacquer layers between said respective opposite barrier layers and said heat-sealing lacquer layers having a weight per unit area in the range of between 1 and 15 grams per meter squared. Furthermore, one of ordinary skill in the art would not have been motivated to provide barrier layers for volatile ingredients in the package of Wardell since Wardell teaches the packaging of sterilized pharmaceutical goods such as gloves etc..

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Miggins whose telephone number is 571-272-1494. The examiner can normally be reached on 1:00-10:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Y Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Miggins Primary Examiner

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MCM May 12, 2005